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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,866	08/20/2003	Leigh T. Canham	124-1052	5193

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,866	CANHAM, LEIGH T.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-86* is/are pending in the application.

4a) Of the above claim(s) *49-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-48 and 86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/000,258 and 09/964,361.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/20/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 46-86 are pending. Claims 70, 74-80, and 82-85 are withdrawn from consideration as being drawn to non-elected invention. Claims 49-69, 71-73, and 81 are withdrawn from consideration as being drawn to a non-elected species. **Claims 46-48 and 86 are under consideration in the instant office action.** Receipt and consideration of Applicants' IDS (submitted 8/20/2003) and remarks/arguments submitted on November 27, 2006 is acknowledged.

Election/Restrictions

Applicant's election of Group I (claims 46-69, 71-73, 81, and 86) in the reply filed on November 27, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, **the election has been treated as an election without traverse** (MPEP § 818.03(a)).

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copies of GB 9524242.6 and GB 9611437.6 have been filed in parent Application Nos. 09/000,258 (now U.S. Patent No. 6,322,895), 09/964,361 (now U.S. Patent No. 6,666,214), and PCT/GB96/01863), filed on 01/30/1998, 09/28/2001, and 08/01/1996, respectively.

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on August 3, 1995. It is noted, however, that applicant has not filed

a certified copy of the GB 9515956.3 application as required by 35 U.S.C. 119(b). The Examiner has reviewed the parent applications and priority document, GB 9515956.3, filed August 3, 1995 in the United Kingdom was not in any of the parent files. The Examiner respectfully requests that Applicants resubmit a certified copy of this priority document.

Specification

The disclosure is objected to because of the following informalities: (1) the word "time" is misspelled as "tim" on page 10, line 1 of the specification; (2) on page 13, line 32 the word "intentionally" is misspelled as "int ntionally"; and (3) the definite article "the" on page 21, line 1, 6th word is misspelled as "th."

Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademark THERMCO® ([0091]) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention lacks patentable utility.

Claims 46-48 and 86 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

Applicants are claiming a method of implantation comprising the step of implanting a sample of resorbable silicon into a living animal or human. Applicants' specification lacks description of a method of implantation and no specific and substantial utility for the claimed method is stated in the instant specification. In paragraph [0061], Applicants speculate that mesoporous silicon, which exhibits resorbable properties, might function as a source of soluble silicon that could produce a locally saturated silicon solution and hence the promotion of apatite deposition. The statement in [0061] is not an assertion of a specific and substantial utility, but merely a guess regarding a possible future use.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46-48 and 86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. The instant specification does not describe any method of implantation of a sample of resorbable silicon into a living animal or human. It is noted that the specification states that bioactive materials may be considered to be any material that is suitable for implantation ([0003]). The doping of calcium into silicon via "ion implantation" is briefly described in [0070], however, this is unrelated to the implantation of resorbable silicon into a living human or animal. In paragraph [0088] of the specification, it is written, "The process of enhanced mineral deposition may be beneficial in the coating of silicon based integrated circuits prior to their implantation in the body;" however this does not constitute an adequate description of a method of implantation of resorbable silicon in a living human or animal to demonstrate possession of the claimed method of implantation. In paragraph [0096] Applicants' suggest that "surgical implants" could be coated with polysilicon in order to increase adhesion to bone. This statement fails to provide adequate description and guidance of the claimed method of implantation of resorbable silicon into a living animal or human to demonstrate possession of the claimed method of implantation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 86 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 86 is vague and indefinite because it is unclear how resorbable silicon can simultaneously be amorphous, polycrystalline, and crystalline.

Claim 86 is vague and indefinite because "resorbable silicon" is a specific single species; therefore the use of comprising language in reference to resorbable silicon is confusing.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46-48 and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolfrom et al. (U.S. Patent No. 4,326,523).

Applicants claim a method implantation comprising the step of implanting a sample of resorbable silicon into a living animal or human (claim 46), wherein the resorbable silicon comprises a region of porous silicon that dissolves over a period of time in a simulated body fluid (claim 47) or which forms part of a bioactive silicon structure (claim 48), wherein the resorbable silicon comprises one or more of amorphous silicon, polycrystalline silicon, and crystalline silicon (claim 86).

Wolfrom discloses in claim 1:

> 1. A method of supplying a micronutrient to meat-producing animals comprising formulating the micronutrient in a slow release, absorbable pellet in combination with a biocompatible, absorbable carrier, and subcutaneously implanting said pellet in a meat-producing animal to thereby slowly release said micronutrient directly into the animal's circulatory system as said pellet is absorbed, said micronutrient being selected from the group consisting of suitable compositions containing iron, copper, selenium, zinc, manganese, iodine, cobalt, molybdenum, chromium, silicon, biotin, vitamin E and vitamin B_{12}, and said absorbable carrier being selected from the group consisting of lactose, fibrin, methylcellulose, collagen, cholesterol, carbowax, beeswax, dibutylphthalate (DBP), polyvinylpyrolidone (PVP), zinc stearate, polyactides including α-hydroxypropionic acid, polyethylene glycol (PEG), sugar-starch combinations and suitable combinations of the above.

The silicon formulated in Wolfram's invented pellets is inherently resorbable silicon, because it is released and absorbed into the animals' circulatory system. Resorbable silicon is

inherently porous, as evidenced by Applicants' remarks in the preliminary amendments submitted on August 20, 2003. The silicon in Wolfram's pellets inherently forms part of a bioactive silicon structure, per Applicants' definition on page 1, lines 10-12 that a bioactive material is any that elicits a specific biological response that results in the formation of a bond between living tissue and that material. The specification does not specify what kind of bond is required for a material to be considered bioactive. The dissolution process inherently results in the formation of hydrogen bonds and other intermolecular interactions between the absorbable silicon and the surrounding tissue. The different morphologies recited in claim 86 cover the gambit of all possible morphologies for a solid substance (e.g. amorphous and crystalline), therefore the silicon in Wolfram's invented pellets inherently meets this limitation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 46, 48, and 86 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 6 of U.S. Patent No. 6,666,214 (USPN '214). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are mutually obvious. Independent claim 46 of the instant application claims a method implantation comprising the step of implanting a sample of resorbable silicon into a living animal or human. Independent claim 1 of USPN '214 claims a method of implantation comprising the step of implanting an electronic device within a living human or animal body, wherein the device includes bioactive silicon. The term bioactive silicon reads on resorbable silicon per Applicants' definition. The remaining limitations of the dependent claims of the instant application are taught by the cited dependent claims of USPN '214 (e.g. polycrystalline silicon as claimed in claim 86 is taught in claim 6 of USPN '214). Therefore, the Examiner concludes that a person of ordinary skill in the art at the time of the instant invention would have found claims 46, 48, and 86 *prima facie* obvious over claims 1-3 and 6 of USPN '214.

Claims 46 and 49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 91-92 of copending Application No. 11/159,340 (copending '340). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and mutually obvious. Independent claim 46 of the instant application claims a method implantation comprising the step of implanting a sample of resorbable silicon into a living animal or human. Independent claim 91 of copending '340 claims a method of

treating an animal or human by (a) implanting into the human or animal a sample of porous silicon, and (b) allowing the tissue growth on the surface of the porous silicon, or allowing the porous silicon to corrode. The corrosion of porous silicon reads on resorbable silicon. The additional step, step (b), recited in claim 91 of copending '340 would obviously occur to the resorbable silicon implanted using the method of the instant application after implantation, because resorbable silicon would be expected to corrode (i.e. dissolve). Therefore, the Examiner concludes that a person of ordinary skill in the art at the time of the instant invention would have found claims 46 and 49 *prima facie* obvious over claims 91-92 of copending '340.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 46-48 and 86 (i.e. all claims under consideration in the instant office action) are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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